Paper No. 53 Filed: March 17, 2016

UNITED STATES PATENT AND TRADEMARK OFFICE BEFORE THE PATENT TRIAL AND APPEAL BOARD

AMNEAL PHARMACEUTICALS LLC, PAR PHARMACEUTICAL, INC., and WOCKHARDT BIO AG, Petitioners,

v.

JAZZ PHARMACEUTICALS, INC., Patent Owner.

Case IPR2015-0547¹ Patent 7,765,107

PETITIONERS PAR PHARMACEUTICAL, INC.'S
AND AMNEAL PHARMACEUTICALS LLC'S RESPONSE
TO PATENT OWNER'S NOTICE REGARDING NEW
ARGUMENTS AND EVIDENCE IN PETITIONERS' REPLY

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P.O. Box 1450 Alexandria, VA 22313-1450

¹ Case IPR2015-01820 has also been joined with this proceeding.



Pursuant to the Board's March 3, 2016 e-mail, Petitioners Par Pharmaceutical, Inc. and Amneal Pharmaceuticals LLC identify the following portions of Patent Owner's Response (Paper No. 46) to which the arguments and evidence that Patent Owner Jazz Pharmaceuticals, Inc. identified in its March 10, 2016 Notice (Paper No. 52) respond:

- 1. The arguments and evidence Jazz identified in Paragraph 1 of its Notice respond to the arguments in Patent Owner's Response starting on page 9, after subheading (c), through page 11, line 9; including Jazz's argument that: "the redactions in Ex. 1004 do not evidence public accessibility before the critical date" (page 10); and "Petitioners ignore that the Briefing Booklet is addressed to a limited Advisory Committee panel that was responsible for reviewing the Xyrem drug application for FDA approval." (page 10).
- 2. The arguments and evidence Jazz identified in Paragraph 2 of its notice respond to arguments in Patent Owner's response starting on page 10, line 8, through page 11, line 9; including Jazz's argument that: "Petitioners ignore that the Briefing Booklet is addressed to a limited Advisory Committee panel that was responsible for reviewing the Xyrem drug application for FDA approval." (page 10). Further, the evidence to which Jazz refers was provided with the Petition. *See* Paper No. 2.



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3. The arguments and evidence Jazz identified in Paragraph 3 of its notice respond to arguments in Patent Owner's response starting on page 5, line 1 (under subheading (a)) through line 13; including Jazz's argument that: "[t]he dates on the documents do not establish public accessibility before the critical date" (page 5). Further, the evidence Jazz refers to was provided with the Petition. *See* Paper No. 1 at 15; *see also* Paper No. 2.

Respectfully Submitted,

Date: March 17, 2016

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CERTIFICATION OF SERVICE (37 C.F.R. §§ 42.6(e)

The undersigned hereby certifies that the above-captioned "Petitioners Par Pharmaceutical, Inc.'s and Amneal Pharmaceuticals LLC's Response to Patent Owner's Notice Regarding New Arguments and Evidence in Petitioners' Reply," was served in its entirety on March 17, 2016, upon the following parties via e-mail:

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